10/568004
APO/RCD/PCT 08 FEB 2006

APPLICATION

FOR

UNITED STATES OF AMERICA

* *

SPECIFICATION

TO ALL WHOM IT MAY CONCERN:

Be it known that I,

Francesca GHIGINI,
Italian citizen
of MILANO - ITALY

have invented certain improvements in

"DEVICE FOR DETECTING ARTERIAL PRESSURE"

of which the following description in connection with the accompanying drawings is a specification, like reference characters on the drawings indicating like parts in the several figures.

IAP9 Rec'd PCT/PTO 08 FEB 2006

The present invention relates to a device for detecting arterial pressure. More particularly, the invention relates to a device suitable to detect arterial pressure, generally known as sphygmomanometer, which is capable of giving maximum objectivity to the measurement made.

BACKGROUND OF THE INVENTION

As is known, the sphygmomanometer was introduced at the end of the 19th century and is still universally used today according to the measurement technique perfected in the early 20th century.

Such instrument, composed of a manometer connected to a chamber that can be inflated by means of an air-bulb, is designed to oppose a known pressure to the arterial pressure and therefore allow to read the pressure values when blood flow is detected, by listening with a stethoscope during decompression of the cuff that contrasts the known pressure, and subsequently, by auscultation, the level at which the action of the cuff no longer affects the detected sounds.

The inflatable chamber, integrated in a cuff that is applied to the arm of the patient, produces on the arm a pneumatic pressure that exceeds the arterial pressure at a certain point of the compression, interrupting the flow of blood downstream of the cuff. Once the arterial pressure has been exceeded by 20-30 mm Hg, decompression of the cuff is performed by means of a pneumatic valve that is normally integrated in the bulb.

During decompression, the operator listens to the sounds produced by the artery, detected by means of a stethoscope that is appropriately placed on the arm. In this manner, the operator detects a series of sounds having mutually different tones, intensities and durations, produced by the arterial pulses, which in turn are a consequence of cardiac activity and of the resistance of the arterial vessel. At this point, the operator must determine which of these pulses represents the systolic value (maximum pressure) and

which one represents the diastolic value (minimum pressure).

The above described measurement of arterial pressure however suffers drawbacks that are due to the fact that the measurement inherently has the following subjective aspects.

Excessively rapid decompression rate: the error due to an excessively rapid decompression rate in the cuff derives from the reaction time of the operator.

When the operator detects the pulse that determines the systolic value or the one that determines the diastolic value, he/she reads on the graduated scale of the manometer the value, which in the meantime has decreased as a function of its decompression rate.

As a consequence of this, medical doctrine prescribes a rate between 2 and 3 mm Hg per second as regards decompression. However, in practice this prescription is commonly ignored, because there is a tendency to reduce the time required for the measurement, underestimating the error made and therefore failing to obtain reliable data.

A second type of error is given by a parallax error, i.e., by an incorrect placement of the operator with respect to the manometer. As is evident, such error can be opposite in sign and variable in meaning, with random characteristics, indeed depending on the position that the operator assumes with respect to the manometer.

Another error is given by the operator's natural tendency to round off the read value to a value that is easy to memorize. This rounding off is usually performed to 5 mm Hg and sometimes to 10 mm Hg.

Yet another error is given by the uncertainty in determining which pulse indicates systolic pressure and likewise which pulse indicates diastolic pressure.

In the first case, the phenomenon that causes so-called supermaximal pressure is known in the doctrine. When decompression begins, one waits to detect the first pulse in the stethoscope. The first pulse normally indicates

the systolic value (maximum pressure). However, the first pulse does not always correspond to flow of blood beneath the inflatable chamber caused by the blood pressure exceeding the pressure that contrasts it by means of the cuff. Actually, with a high-intensity wrist pulse it is possible to detect pulses produced by the impact of the arterial pulsation against the edge of the cuff that constitutes the obstacle that cannot be passed until its pressure has dropped below the level of the arterial pressure.

Substantially, this noise may be audible with a variable acoustic level depending on the intensity of the wrist pulse. In the presence of a "strong" pulsation, these supermaximal pulses must be discriminated by the operator by comparing their intensity with the subsequent pulses.

In the second case, there is uncertainty in determining which pulse can be defined as a diastolic pulse, i.e., the pulse that indicates the minimum pressure. Determination of diastolic pressure has always been more difficult to define, and uniformity of its results is currently unsolved.

Electronic sphygmomanometers are currently known which use the principle of the manual sphygmomanometer but replace auscultation by the operator with detection of the signal by means of a microphone or by detecting the sphygmic pulse in the form of a pneumatic oscillation within the circuit of the instrument, caused by the arterial pulsation itself.

The first method is the closest possible analogy to stethoscopic auscultation, with the difference of replacing human abilities in hearing and processing the signal with electronic means that can offer different results due to obvious inherent characteristics.

The second technique has greater operating differences, since it is not based on the same element described above, i.e., the noise generated by blood flow, but on a different element, such as the pneumatic oscillation inside the circuit of the instrument, caused by the pulsation itself. By processing with increasingly sophisticated algorithms, an attempt has been made to attain a result that is as close as possible to the result that can be

obtained with human auscultation, but currently it is not possible to have a completely reliable measurement.

SUMMARY OF THE INVENTION

The aim of the present invention is to provide a device for detecting arterial pressure that substantially allows to improve the precision of the measurement.

Within this aim, an object of the present invention is to provide a device for detecting arterial pressure that allows to eliminate the drawbacks due to an excessively high decompression rate, to parallax error, to the operator's tendency to round off the measured value, and finally to the uncertainty in determining the pulse to be defined as systolic and the pulse to be defined as diastolic.

A further object of the present invention is to provide a device for detecting arterial pressure that maintains the central role of human assessment in pressure measurement, supporting it with the aid of electronic means.

A further object of the present invention is to provide a device for detecting arterial pressure that is highly reliable, relatively simple to manufacture, and at competitive costs.

This aim and these and other objects that will become better apparent hereinafter are achieved by a device for detecting arterial pressure with high measurement precision, comprising a cuff with inflatable chamber, adapted to be placed around the arm of a patient; means for introducing air to inflate said cuff, and decompression means suitable to decompress said inflatable chamber, characterized in that it comprises means adapted to detect and store all the sphygmic pulses generated by arterial pressure and to identify the pulses that correspond to the appearance and disappearance of the wrist beat, detected by means of a technique for detecting sphygmic pulses generated by arterial pressure that requires the intervention and judgment of an operator.

BRIEF DESCRIPTION OF THE DRAWINGS

Further characteristics and advantages of the invention will become better apparent from the description of a preferred but not exclusive embodiment of the device according to the present invention, illustrated by way of non-limiting example in the accompanying drawing, wherein the only figure is a block diagram of the apparatus according to the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

With reference to the figure, the device according to the present invention, generally designated by the reference numeral 1, comprises air pumping means 2, for example of the manual or electric type, which are connected to a cuff 3, inside which an inflatable chamber is accommodated. Decompression means 4, conveniently constituted by a compression valve, are adapted to perform a constant and controlled decompression of the cuff 3, as prescribed by medical doctrine to perform an accurate measurement.

The device further comprises means 5 for complete and instantaneous venting of the air of the cuff 3. The venting means 5 are constituted, for example, by a valve that allows to discharge instantly, at the operator's choice, the air from the cuff 3. As an alternative, it is possible to use as a vent the same decompression valve, used appropriately.

The device according to the invention further has pressure transducer means 6, which are adapted to detect electronically all the sphygmic pulses generated by arterial pulsation and are connected to storage means 7 adapted to store said pulses. The means 6 for detecting the sphygmic pulses further allow to identify the pulses that correspond to the appearance and disappearance of the pulse, detected by means of any detection method that provides for the intervention of the operator and for his subjective judgment.

The transducer means continuously detect the value of the pressure of the cuff, like a normal manometer does. This value is reported in real time

by the display and recorded together with the detection of the sphygmic pulses. Accordingly, once the measurement has ended, the operator can analyze, on the display, a listing in which, next to the pressure values expressed for example in mm Hg (or KPa), he/she can read, at the pressure pulses, a value that indicates their sphygmic intensity.

The operator, when he perceives the stethoscope pulses (or pulses detected in another manner) that correspond to the systolic and diastolic pressure, presses a button of the device to "mark" these values on the digital scale of the device.

Substantially, therefore, the user performs a manual detection of the pulses by means of the conventional stethoscope (or, as mentioned, by means of any other method), but the means 6 for detecting sphygmic pulses are associated with said detection and allow to identify the pulses that correspond to systolic pressure and to diastolic pressure.

Storage of the data, i.e., of the pulses and therefore of the chart, allows to determine with certainty the pulses that actually correspond to the maximum and minimum values of arterial pressure, performing this analysis after detection by means of the stethoscope.

Substantially, therefore, the operator has control over the measurements performed manually, and accordingly can associate the precision of manual detection with a device that allows to eliminate the previously mentioned uncertainties that are inherent in the measurement.

The device is further provided with display means 8, which are adapted to display at least the following detected pressure levels: in real time, at the stored times, with previous measurements (i.e., measurement history).

The device according to the present invention is capable of transferring the detected results to other storage and/or printout means.

It should be noted that the measurement method currently in use, i.e., with a cuff provided with an inflatable chamber, prescribes the use of an

inflatable chamber that is proportionate to the size of the arm of the patient. However, since in practice it is not possible to have a cuff for each patient, medical doctrine has established three types of cuffs for three different types of patient. However, very often an operator does not comply with these indicators and always uses a single standard cuff.

The use of a standard cuff, however, is another source of error, which adds to the previously described errors that are inherent in the measurement.

For this purpose, the device according to the present invention uses a cuff 3 on which a scale is printed along its entire longitudinal side, said scale indicating, when the cuff is applied, the circumference of the arm of the user. This information can be used, by entering it in the device according to the invention, as a corrective factor for the arterial pressure measurement that is made, accordingly complying with the criteria of using a cuff for each type of patient.

In practice it has been found that the device according to the present invention allows to perform a manual measurement with a stethoscope of the arterial pressure of a patient, with the association of means adapted to detect the sphygmic pulses generated by arterial pressure and to then identify the pulses that correspond to the appearance and disappearance of the pulse detected by means of the stethoscopic technique. These pulses correspond respectively to systolic pressure and to diastolic pressure.

The operator, therefore, can perform a manual measurement with the aid of a sort of electronic measurement for control and confirmation. The device according to the invention allows to store the chart of the pulses in order to perform a subsequent verification thereof, so as to determine assuredly the pulses that actually correspond to the maximum and minimum values of the arterial pressure.

The device thus conceived is susceptible of numerous modifications and variations, within the scope of the appended claims. All the details may be replaced with other technically equivalent elements.

In practice, the materials used, as well as the contingent shapes and dimensions, may be any according to requirements and to the state of the art.

The disclosures in Italian Patent Application No. MI2003A001683 from which this application claims priority are incorporated herein by reference.